SONOMA BIOTHERAPEUTICS

SCHEDULE OF ASSESSMENTS: SCREENING AND PRETREATMENT PERIODS

SONOMA BIOTHERAPEUTICS | SBT777101-02

Protocol: Version 3.0 | 01 May 2025

	Screening [a]	Pretreatment [b]		
		Apheresis [c]	Pre-infusion	Biopsy
Study Day (visit window)			-10 to -4	-7 to 1
Procedure				
Informed consent	•			
Eligibility criteria	•	•	•	
Demographics	•			
Medical history [d]	•		•	
Prior/Concomitant medications	•	•	•	
Vital signs	•		•	
Full physical exam [e]	•			
Directed dermatologic physical exam [e]			•	
ICE			•	
Height	•			
Weight	•		•	
12-lead triplicate ECG	•		•	
Chest X-ray			•	
Skin biopsy and corresponding lesion photograph [f]	•			•
Skin photography of affected lesions [g]	•		•	
Vein assessment [h]	•	•		
Apheresis [c]		•		
Infectious disease serology [i]	•			
TB screening [j]	•			
Serum pregnancy test	•		•	
Lipid tests [i]			•	
Coagulation [i]	•		•	
Hematology [i]	•		•	
Clinical chemistry [i]	•		•	
Urinalysis [i]	•		•	
Markers of acute inflammation [j]			•	

Continued on reverse

	Screening [a]	Pretreatment [b]		
		Apheresis [c]	Pre-infusion	Biopsy
Study Day (visit window)			**-10 to -4**	**-7 to 1**
Procedure				
CRP and ESR [j]			●	
Lesion count [k]	●		●	
Subject HiSQOL score [l]	●		●	
NRS-30 [l]	●		●	
Collect date of the first day of the last menstrual period	●		●	
Blood samples for PK (ddPCR)			●	
PBMC sample for cellular immunogenicity			●	
Serum sample for ADA			●	
Plasma for exploratory markers	●		●	
Serum for exploratory markers	●		●	
PBMC for exploratory biomarkers	●		●	
PBMC samples for RCL			●	
Concomitant medications	●	●	●	●
Adverse events [l]	●	●	●	●

A = abscess; **ADA** = anti-drug antibody; **APH** = apheresis; **CRP** = C-reactive protein; **ddPCR** = droplet digital polymerase chain reaction; **dT** = draining tunnel (fistula/sinus); **ECG** = electrocardiogram; **ESR** = erythrocyte sedimentation rate; **HiSCR** = hidradenitis suppurativa clinical response; **HiSQOL** = Hidradenitis Suppurativa Quality of Life; **ICE score** = Immune Effector Cell-Associated Encephalopathy Score; **N** = inflammatory nodule; **PK** = pharmacokinetic; **RCL** = replication competent lentivirus; **TB** = tuberculosis; **UV** = unscheduled visit

a. The Screening period is expected to last approximately 4 weeks (but up to 2 months is permitted).

b. The Pretreatment period is expected to last approximately 6 weeks (but up to date of drug product expiration is permitted.

c. Apheresis should be scheduled and performed as soon as possible but no later than 4 weeks after enrollment and the subject enters the Pretreatment period.

d. Medical history to include history of HS flares and treatments for flares in the 6 months prior to screening.

e. For all physical examinations, whether full or directed, the dermatologic examination should include total N, A, and dT counts.

f. Pretreatment skin biopsy (6-mm punch biopsy) is to be performed after the pre-infusion confirmation of eligibility, up to 7 days before study drug administration. There is an option to add a skin biopsy during the screening period. Please photograph the lesion that is to be biopsied. Please refer to the *Biopsy Manual* for further information.

g. Photographic documentation of all affected anatomic regions should be obtained. Photographs at other timepoints should be taken at the discretion of the investigator.

h. Assessment of vascular access and if central line is indicated [vs peripheral intravenous catheter or peripherally-inserted central catheter (PICC)] for apheresis and/or administration of SBT777101 should be determined by the Principal Investigator with subject input.

i. Tests included in laboratory assessments are described in protocol Appendix C. Fasting glucose should be collected at the pretreatment visit and as clinically indicated.

j. Markers of acute inflammation for safety assessment include ferritin, IL-6, IFNγ, CRP, and ESR.

k. Lesion counts will be used to calculate HiSCR 50, 75 and 90 as well IHS4.

l. All SAEs plus any AE that is the result of a protocol-specified procedure or intervention will be collected from the signing of the ICF until study drug administration.